

**REMARKS**

Claims 1-38, 40, 43, 44, and 65-108 are pending in this application. By this Amendment, claim 1 is amended and claims 104-108 are added. No new matter has been added by these amendments. Reconsideration of the application based on the above amendments and the following remarks is respectfully requested.

**Applicants respectfully request that, because this application has been pending for more than five years and has received more than three Office Actions, this application should be considered "special" and a Supervisory Patent Examiner should review this application in order to more promptly and efficiently advance the prosecution. (See MPEP §707.02).**

**I. Personal Interview**

Applicants appreciate the courtesies shown to Applicants' representative by Examiner Yabut in the December 15, 2009 Personal Interview. Applicants' separate record of the substance of the interview is incorporated into the following remarks.

**II. Election of Species/Restriction Requirement**

Claims 24-35, 43 and 65-103 have been withdrawn from consideration. MPEP §821.04(b) recites, in relevant part, "withdrawn process claims which depend from or otherwise require all the limitations of an allowable product claim will be considered for rejoinder." Accordingly, rejoinder of the method claims 65-103 is respectfully requested upon the allowance of any product claim from which they depend.

**III. 35 U.S.C. §102 Rejections**

The Office Action rejects claims 1-2 and 12-17 under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,355,010 to Barbut; and claim 3 under 35 U.S.C. §103(a) as being unpatentable over Barbut. The rejections are respectfully traversed.

**A. Claim 1**

Independent claim 1 recites that at least one sealing surface is adapted to secure the section of tissue by pressure applied to the section of secured tissue between the first and second portions when the first and second portions are brought together.

Barbut discloses opposing structures 214 (alleged first and second portions) that include notches 219 (alleged at least one sealing surface), which help in attaching the intercostal arteries 14 with the engaging outlets 212 (alleged hole) when the opposing structures 214 are closed. However, the notches 219 are not designed to apply pressure to the intercostal arteries 14 to secure the tissue between the first and second portions. Pressure applied by the notches 219 would act to occlude the intercostal arteries 14 contrary to the intent of the perfusion chamber 206.

Therefore, for at least these reasons, Barbut fails to anticipate claim 1. Thus, claim 1 is patentable over Barbut, and claims 2, 3 and 12-17 are patentable for at least their dependency from claim 1, as well as for the additional features they recite.

**B. Claims 104 and 105**

Claim 104 recites the at least one sealing surface and one of the first and second portions being disposed on opposite sides of the section of secured tissue; and claim 105 recites the at least one sealing surface being only unitary with the other of the first and second portions.

Barbut's notches 219 (alleged sealing surface) are not unitary with only one of the opposing structures 214 because the notches 219 are located and required to be on both opposing structures 214. Thus, Barbut fails to disclose at least one sealing surface being only unitary with the other of the first and second portions.

**C. Claim 106**

Claim 106 recites the at least one sealing surface being planar and disposed such that the section of secured tissue contacts and extends along the planar surface.

Barbut's notches 219 do not have at least one sealing surface that is planar. Furthermore, Barbut does not disclose any sealing surface that is planar and disposed such that the section of secured tissue contacts and extends along the planar surface.

**D. Claims 15 and 16**

Claim 15, and similarly claim 16, recite the relative movement permitted by the engagement of the pre-positioning structure and the complementary pre-positioning structure comprises a linear movement that allows the first and second portions to be brought together, while maintaining the first sealing surface substantially parallel to the second sealing surface.

The Office Action equates Barbut's hinge 218 to the claimed pre-positioning structure. As discussed with and agreed upon by Examiner Yabut at the personal interview, linear movement is defined as moving in a direction resembling a line and one of ordinary skill in the art would not interpret this claim term to mean at a constant rate, as asserted in the Office Action. Further, Examiner Yabut is unable to prove that Barbut's hinge 218 would even move at a linear or constant rate, and thus such an interpretation is simply unreasonable. Barbut's hinge 218 is not capable of providing linear movement and is only capable of providing pivoting movement. Thus, Barbut fails to anticipate all of the features of claims 15 and 16.

Accordingly, withdrawal of the rejections is respectfully requested.

**IV. 35 U.S.C. §103 Rejection**

The Office Action rejects claims 4-8, 36-38 and 40 under 35 U.S.C. §103(a) as being unpatentable over Barbut in view of U.S. Patent No. 6,726,651 to Robinson. The rejection is respectfully traversed.

**A. Claim 4**

Dependent claim 4 recites wherein the chamber is designed to collect gas separate from a fluid flow through the first fitting, the chamber and the hole.

The Office Action admits that Barbut fails to disclose the above-mentioned features of claim 4. As discussed during the personal interview, the Office Action asserts that the features of claim 4 are obvious or inherent within the cannula and/or chamber 1220 of Robinson. Applicants respectfully disagree.

The only express disclosure regarding gaseous bubbles in Robinson is at col. 17, lines 21-27, which states that the suction/cardioplegia lumen 611 is changed from a cardioplegia source to a suction source, enabling withdrawal of fluid and embolic debris such as, gaseous bubbles from the region upstream of the first occlusion member 603. Therefore, Robinson discloses a method of removing gaseous bubbles trapped in the ascending aorta (the region upstream of the first occlusion member 603) through the distal suction/cardioplegia opening 603. Thus, Robinson fails to expressly disclose or suggest any feature of the described cannula that is designed to collect gas separate from the fluid flow through the first fitting, the chamber and the hole.

MPEP §2112(IV) states that simply because a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Furthermore, MPEP §2112(IV) requires the

Examiner to provide objective evidence and/or technical reasoning to reasonably support the conclusion of inherency. As discussed during the personal interview, because the Examiner has not, and Applicants believe cannot, make the requisite showings, the above-mentioned feature of claims 4 is allowable over Barbut and Robinson.

**B. Claim 107**

Claim 107 recites an upper portion of the first portion opposite of the hole is designed to collect gas separate from a fluid flow through the first fitting, the chamber and the hole.

Further to the arguments above regarding claim 4, Robinson also fails to disclose or suggest an upper portion opposite of the hole that is designed to collect gas, and there is no rationale to modify Barbut to achieve the above-mentioned features.

**C. Claim 36**

Claim 36 recites a portion extending from the cannula body that defines a lumen that is in fluid communication with the first fitting; a flange formed on the portion extending from the cannula body; and a securing feature on the portion extending from the cannula body, wherein the flange and the securing feature facilitate connecting the lumen to the organ such that the lumen allows fluid flow from the external fluid flow system into the organ.

As discussed during the personal interview with Examiner Yabut, the Office Action does not address any of these features of independent claim 36. Because Examiner Yabut could not provide an adequate articulated reason during the personal interview as to how claim 36 would be rejected over Barbut in view Robinson, and Applicants believe cannot, make the requisite showings, the above-mentioned features of claims 36 are allowable over Barbut and Robinson.

Accordingly, withdrawal of the rejection is respectfully requested.

**V. 35 U.S.C. §103 Rejection**

The Office Action rejects claims 9-11 under 35 U.S.C. §103(a) as being unpatentable over Barbut in view of U.S. Patent No. 4,800,879 to Golyakhovsky. The rejection is respectfully traversed.

**A. Claim 9**

Dependent claim 9 recites the cannula further comprising at least one fixing member on one of the first and second portions, and at least one compression strap arranged to wrap around at least part of the first portion and at least part of the second portion and to engage the fixing member so that the first and second portions are brought together.

The Office Action admits that Barbut fails to disclose the above-mentioned features of claim 9. As discussed during the personal interview, the Office Action asserts that these features of claim 9 are disclosed by Golyakhovsky's toothed latches 14a and 14b and that it would have been obvious to apply this structure to Barbut's perfusion chamber 206. Applicants respectfully disagree.

In the Office Action and during the personal interview, Examiner Yabut did not provide a sufficient rationale as to why one of ordinary skill in the art at the time of the invention would have modified Barbut's perfusion chamber 206 with Golyakhovsky's toothed latches 14a and 14b. The Office Action's currently articulated rationale for the modification (in order to facilitate sealing of the tissue by latching the first and second portions together while minimizing trauma to the tissue) is inapposite.

In particular, a person of ordinary skill in the art at the time of the invention would not have had a good reason to pursue the claimed combination of features because: (1) Golyakhovsky's toothed latches 14a and 14b structures would require that significant modifications be made to Barbut's side walls of either opposing structure 214 (i.e., teeth molded into the surface); and (2) there was no recognized need or problem in Barbut for a

latch on the opposing structure 214. Thus, there is no sufficient rationale for one of ordinary skill in the art at the time of the invention to modify Barbut's opposing structure 214 with Golyakhovsky's toothed latches 14a and 14b to achieve the above-mentioned features of claim 9.

Therefore, because rejections based on obviousness cannot be sustained by mere conclusory statements and there is no sufficient rationale to support the conclusion of obviousness as to why one of ordinary skill in the art at the time of the invention would have modified Barbut's perfusion chamber 206 with Golyakhovsky's toothed latches 14a and 14b, Barbut and Golyakhovsky, and any combination thereof, fail to disclose or suggest the above-mentioned features of claim 9.

**B. Claim 10**

Dependent claim 10 recites a sealing ring disposed between the first and second portions, the compression strap extending from the sealing ring.

The Office Action admits that Barbut fails to disclose the above-mentioned features of claim 10. As discussed during the personal interview, the Office Action asserts that Golyakhovsky discloses these features of claim 10 and that it would have been obvious to apply this structure to Barbut's perfusion chamber 206. Applicants respectfully disagree.

Golyakhovsky fails to disclose a sealing ring. The Office Action states that Golyakhovsky disclose a sealing ring at the top portion of arm 1. However, as discussed during the personal interview with Examiner Yabut, the only structure at the top portion of arm 1 is a cavity 9 with a balloon 13. Please note that a sealing ring is a known term of art and a ring is defined as a circular object, form, line, or arrangement with a vacant circular center. This definition does not fit any of the structures described in Golyakhovsky.

Moreover, even if Examiner Yabut were to introduce the alleged sealing ring (elastomeric seal 883) from Valley into the rejection, the modification of Barbut's perfusion

chamber 206 would not be possible. As discussed during the personal interview, Barbut's opposing structure 214 has matching notches 219 (alleged sealing surface) that would not accommodate the use of a sealing ring because the ring would fall out of place and would not facilitate entry of the intercostal arteries 14 when the opposing structure 214 are opened and closed.

Furthermore, Golyakhovsky and Valley fail to disclose a compression strap extending from the sealing ring. As discussed with and agreed upon during the personal interview with Examiner Yabut, the structure of the compression strap in Applicants' Fig. 22 appears novel (a compression strap extending from a sealing ring). Applicants assert that claim 10 includes allowable features because there is no sufficient rationale for one of ordinary skill in the art at the time of the invention to combine Golyakhovsky's toothed latches 14a and 14b with Barbut's perfusion chamber 206 and Valley's elastomeric seal 883 to arrive at all of claim 10's features. In particular, the features of claim 10 would not have been predictable to one of ordinary skill in the art. The mere fact that references can be combined or modified does not render the resultant combination obvious in the absence of predictability to one of ordinary skill in the art.

**C. Claim 108**

Claim 108 recites the sealing ring being integral with the compression strap.

Further, to the arguments above regarding claim 10, there is no rationale to modify Valley's elastomeric seal 883 such that it is integral with Golyakhovsky's toothed latches 14a and 14b.

Accordingly, withdrawal of the rejection is respectfully requested.

**VI. 35 U.S.C. §103 Rejection**

The Office Action rejects claims 18-23 and 44 under 35 U.S.C. §103(a) as being unpatentable over Barbut in view of U.S. Patent No. 5,814,016 to Valley. The rejection is respectfully traversed.

**A. Claim 18**

Claim 18 recites at least one sealing ring disposed between the top and bottom portions.

As discussed above, the modification of Barbut's perfusion chamber 206 with the alleged sealing ring (elastomeric seal 883) from Valley would not be possible. In the Office Action and during the personal interview, Examiner Yabut did not provide a sufficient rationale as to why one of ordinary skill in the art at the time of the invention would have modified Barbut's perfusion chamber 206 with Valley's elastomeric seal 883. The Office Action's currently articulated rationale for the modification (in order to provide a seal to avoid leaks) is inapposite.

In particular, a person of ordinary skill in the art at the time of the invention would not have had a good reason to pursue the claimed combination of features because: (1) Barbut's opposing structure 214 has matching notches 219 (alleged sealing surface) that would not accommodate the use of a sealing ring because the ring would fall out of place and would not facilitate entry of the intercostal arteries 14 when the opposing structure 214 are opened and closed; and (2) Barbut already has matching notches 219 acting as sealing surfaces for preventing leaks. Thus, there is no sufficient rationale for one of ordinary skill in the art at the time of the invention to modify Barbut's opposing structure 214 and matching notches 219 with Valley's elastomeric seal 883 to achieve the above-mentioned features of claim 18.

Therefore, because rejections based on obviousness cannot be sustained by mere conclusory statements and there is no sufficient rationale to support the conclusion of

obviousness as to why one of ordinary skill in the art at the time of the invention would have modified Barbut's perfusion chamber 206 with Valley's elastomeric seal 883, Barbut and Valley, and any combination thereof, fail to disclose or suggest the above-mentioned features of claim 18.

Accordingly, withdrawal of the rejection is respectfully requested.

**VII. Conclusion**

In view of the foregoing, it is respectfully submitted that this application is in condition for allowance. Favorable reconsideration and prompt allowance are earnestly solicited.

Should the Examiner believe that anything further would be desirable in order to place this application in even better condition for allowance, the Examiner is invited to contact the undersigned at the telephone number set forth below.

Respectfully submitted,

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Attachment:

Request for Continued Examination

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